Evidence Table

Clinical Area: Multislice CT scanning for coronary heart disease.


Study Type: Comparison of diagnostic tests.

Study Aim: To determine the diagnostic accuracy of the 64-slice multidetector computed tomographic (MDCT) coronary angiography compared to stress nuclear imaging for the detection of an acute coronary syndrome (ACS) or 30 day major cardiac adverse events in low-risk chest pain patients.

Outcomes:
- Primary: Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Design
- Number of subjects: N=92 included, 85 analyzed.
- Description of study population: These were patients seen in the emergency department of suburban teaching hospital in Michigan USA between September 2004 and March 2005. Their mean age was 50 years, almost 50% were men, 87% had chest pains, 33% had hypertension, 25% hyperlipidemia, 9% diabetes, 24% tobacco abuse, and 54% family history of CAD. 55% had normal ECG at admission.
- Inclusion criteria: The study included patients ≥18 years seen in an emergency department (ED) for chest pain or symptoms suggestive of acute coronary syndrome, and with negative serial ECG and cardiac marker results in the ED and observation unit. Patients were identified at low risk according to their symptoms, examination, tests, and initial ECG results.
- Exclusion criteria: Positive initial cardiac results or new ischemic ECG changes, pregnancy, history of a CAD (≥30% stenosis, cardiomyopathy, CHF with an ejection fraction <45%), a contraindication to iodinated contrast or B-blocker drugs, atrial fibrillation, markedly irregular rhythm, renal insufficiency, or having a CT imaging or contrast within the past 48 hours.
- Power: Not discussed.
- Intervention / procedure: Study patients were admitted to the ED observation unit for the chest pain diagnostic protocol (cardiac monitoring, serial ECG, and cardiac marker tests) 4 hours after arrival. Those with abnormal markers had repeat tests and ECG at 8 hours. If these latter tests were negative the patients received a stress nuclear imaging test followed by MDCT coronary angiography using 64-slice multidetector CT scanners. Stenosis ≥50, calcium scores >400 or coronary calcium encroaching on >50% of the lumen were considered as positive. Patients were treated based on the findings of both tests, and then followed up for evidence of ACS or major adverse events within 30 days of their initial visit. Those with positive tests suggesting unstable angina underwent cardiac catheterization to confirm the diagnosis.
• **Follow-up duration and source of follow-up data:** Patients were followed up for 30 days, by return visits, telephone interviews, and chart reviews for any major adverse cardiac events.

**Validity**

• *Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?* The interpreters of the MDCT and stress nuclear imaging were blinded to the results of the other test. Invasive coronary angiography the gold standard was not performed on all patients.
• *Was “normal” defined?* Yes.
• *Appropriate spectrum of disease?* No.
• *Consecutive patients?* Not discussed.
• *Methods described in enough detail to enable you to replicate the test?* Yes.
• *Reproducible results?* Yes.

• **Conclusions regarding validity of methods:**

One main limitation of the study is not performing coronary catheterization, the gold standard on all patients. This was conducted on only 12 (13%) of the patients. The authors used clinical markers and outcome as a surrogate gold standard. Moreover, 7 (7.6%) of the study participants were not included in the analysis due to uninterpretable MDCT images.

**Results:**

• 7 patients (8%) were diagnosed with an acute coronary syndrome defined by significant coronary artery stenosis. These underwent invasive cardiac angiography which showed an average stenosis of 88% ± 9% (range 70%-90%). 6 were treated with percutaneous coronary intervention, and one received medical treatment only.
• Both stress nuclear test and MDCT were negative in 66 out of 85 (78%) patients analyzed, and positive in six patients (7%).
• The two tests had discordant results in 13 /85 patients (15%)

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<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV*</th>
<th>NPV**</th>
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<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
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<tr>
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<td>% (95%CI)</td>
<td>% (95%CI)</td>
<td>% (95%CI)</td>
<td>% (95%CI)</td>
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<tr>
<td>Stress nuclear imaging</td>
<td>5/7 71%  (36% -92%)</td>
<td>70/78 90% (81% -95%)</td>
<td>5/13 38% (18% -64%)</td>
<td>70/72 97% (90% -99%)</td>
</tr>
<tr>
<td>MDCT</td>
<td>6/7 86% (49% -97%)</td>
<td>72/78 92% (84% -96%)</td>
<td>6/12 50% (25% -75%)</td>
<td>72/73 99% (93% -100%)</td>
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† Using clinical markers and outcomes as gold standards.
* Positive predictive value
** Negative predictive value

**Accuracy† of Myocardial perfusion imaging and MDCT (N=85)**

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Authors’ Conclusions:

The authors concluded that the accuracy of MDCT is at least as good as that of the stress nuclear imaging for the detection and exclusion of ACS in low-risk chest pain patients. They pointed out some of the limitations to their study.

Reviewer’s Conclusions:

This relatively small, single center, study had several limitations mainly not comparing the results of the nuclear stress test and MDCT to a gold standard, and using surrogate clinical markers instead. Cardiac catheterization was performed among all seven patients diagnosed as positive with the two index tests, but was only conducted among 5 patients out of the 13 with discordant results between the two test. The authors did not discuss why and how they selected patients to undergo cardiac catheterization for verification. Moreover, the treating physicians were not blinded to the results of both the MDCT and nuclear scan, which may be a potential source of bias. Patients were managed based on the results of both test, thus the effect of either on the treatment decision cannot be determined. Another limitation of the study was excluding patients with uninterpretable MDCT images from the analysis, which would overestimate the diagnostic accuracy of the test. The authors concluded that MDCT is at least as good as that of the stress nuclear imaging for the detection and exclusion of ACS, while the nuclear imaging stress test is known to be an imperfect test.